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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,286	09/11/2003	Randall S. Hickle	END0881USANP	5325

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EXAMINER	
PATEL, NIHIR B	

ART UNIT	PAPER NUMBER
3772	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/660,286	HICKLE ET AL.	
	Examiner	Art Unit	
	Nihir Patel	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *September 11th, 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09.11.2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11.26.04; 12.8.04*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. Applicant has indicated co-pending applications in the first paragraph of the specification. The first page of the specification should be updated to clarify the status of all related applications noted in the first paragraph of the specification. The status of nonprovisional parent application's) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims **1-3, 5, 6, 9-12, 14-16, 18, 19 and 22-25** are rejected under 35 U.S.C. 102(b) as being anticipated by Lampotong et al. (US 6,131,571).

4. **As to claim 1,** Lampotong teaches a ventilation apparatus and anesthesia delivery system that comprises a variable size orifice system connected to a gas source **200 and 202 (see figure 2)** wherein said variable size orifice system **132** has a gas outflow opposite of said gas source; and a sensor system **100, 104, 108 and 120 (see figure 2)** connected to said gas outflow wherein said sensor system can be used to verify a patient receives the appropriate gas from said gas source.

5. **As to claims 2 and 15,** Lampotong teaches an apparatus wherein the gas source comprises of a gas containment dispenser **(see column 18 lines 1-10)**.

6. **As to claims 3 and 16,** Lampotong teaches an apparatus wherein the gas containment dispenser is an in-house gas supply **(see column 18 lines 15-25)**.

7. **As to claims 5 and 18,** Lampotong teaches an apparatus wherein the gas containment dispenser comprises of oxygen **(see column 18 lines 1-25)**.

8. **As to claims 6 and 19,** Lampotong teaches an apparatus wherein the gas containment dispenser comprises of nitrous oxide **(see column 16 lines 25-35)**.

9. **As to claims 9 and 22,** Lampotong teaches an apparatus wherein the variable size orifice system further comprises of a pressure relief valve **130** and a control unit **34** connected to a variable size orifice valve **132 (see column 15 lines 35-45 and column 20 lines 20-30)**.

10. **As to claims 10 and 23,** Lampotong teaches an apparatus wherein the variable size orifice system further comprises of a high side pressure sensor **100** connected between said pressure relief valve **130** and said variable size orifice valve **132** and a low side pressure sensor **108** connected to said gas outflow **(see figure 2)**.

11. **As to claims 11 and 24,** Lampotong teaches an apparatus wherein the variable size orifice system further comprises of and n-way valve connected to n discrete orifices wherein n is the number of pressure levels produced from said variable size orifice system **(see column 8 lines 35-45)**.

12. **As to claims 12 and 25,** Lampotong teaches an apparatus wherein the sensor system further comprises gas sensor **(see column 13 lines 25-35)**.

13. **As to claim 14,** Lampotong teaches a ventilation apparatus and anesthesia delivery system that comprises a variable size orifice system connected to a gas source **200 and 202 (see figure 2)** wherein said variable size orifice system **132** has a gas outflow opposite of said gas source; a sensor system **100, 104, 108 and 120 (see figure 2)** connected to said gas outflow wherein said sensor system can be used to verify a patient receives the appropriate gas from said gas source; a control unit **34** connected to said variable size orifice system **132** and said sensor system **100, 104, 108 and 120** wherein said control unit can be used to control the gas flow through said variable size orifice system and to control delivery of a sample of said gas outflow to said senor system **(see column 15 lines 35-45 and column 20 lines 20-30).**

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claim **27** rejected under 35 U.S.C. 103(a) as being unpatentable over Lampotong et al. (US 6,131,571).

17. **As to claim 27,** Lampotong teaches a method step of calibrating the gas supply and monitoring system; verifying functionality of the sensors; measuring gas concentration; verifying the appropriate gas output and concentration level; and delivering gas to the patient **(see column 19 lines 15-65)**.

The claimed method steps would have been obvious because they would have resulted from the use of the device of Lampotong.

18. Claims **4 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampotong et al. (US 6,131,571) in view of Frankie et al. (US 6,347,627).

19. **As to claims 4 and 17,** Lampotong substantially discloses the claimed invention; see rejection of claims 1, 2, 14 and 15 above, but does not disclose a gas containment dispenser that is portable. Frankie discloses an apparatus that does provide a gas containment dispenser that is portable **(see abstract)**. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lampotong's invention by providing a gas containment dispenser that is portable as taught by Frankie so that it is useful for underwater, firefighting and outer space applications.

20. Claims **7, 8, 20 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampotong et al. (US 6,131,571) in view of Sackner et al. (US 6,015,388).

21. **As to claims 7, 8, 20 and 21,** Lampotong substantially discloses the claimed invention; see rejection of claims 1, 2, 14 and 15 above, but does not disclose a gas containment dispenser that comprises a sedative and analgesic. Sackner teaches an apparatus that does provide a gas containment dispenser that comprises a sedative and analgesic **(see column 11 lines 15-20).** Therefore, it would have been obvious to one having ordinary skill in the art at the time the

invention was made to modify Lampotong's invention by providing a gas containment dispenser that comprises a sedative and analgesic as taught by Sackner in order to make the surgical process easier for the patient.

22. Claims **13 and 26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampotong et al. (US 6,131,571) in view of Clough et al. (US 4,939,647).

23. **As to claim 13 and 26,** Lampotong substantially discloses the claimed invention; see rejection of claims 1, 2, 14 and 25 above, but does not disclose a gas sensor is a galvanic cell. Clough discloses an apparatus that does provide a gas sensor is a galvanic cell **(see column 5 lines 50-65).** Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lampotong's invention by providing a gas sensor is a galvanic cell as taught by Cough in order to output a greater or lesser signal that is fed to a comparator in the electronics.

24. Claims **28-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampotong et al. (US 6,131,571) in view of Seabron (US 6,248,068).

25. **As to claims 28-30,** Lampotong substantially discloses the claimed invention; see rejection of claim 27 above, but does not disclose an alarm for checking functionality of the sensors, indicating if the gas concentration is outside an acceptable range. Seabron discloses an apparatus that does provide a alarm **(see figure 1)** for checking functionality of the sensors, indicating if the gas concentration is outside an acceptable range. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lampotong's invention by providing an alarm as taught by Seabron in order to let the user know if the sensors are not working or if the gas concentration is out of range.

Double Patenting

26. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

27. Claims **1 and 14** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim **12** of U.S. Patent No. 6,938,619. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between claim 1 of the current application and claim 12 of patent '619 lies in the fact that the patent claim 12 includes many more elements and is thus much more specific. Thus the invention of claim 12 of patent '619 is in effect a "species" of the "generic" invention of claim 1 of the current application. It has been held that the generic invention is "anticipated" by the "speices". ***See In re Goodman,* 29 USPQ2d 2010 (Fed. Cir. 1993).** Since claim 1 of the current application is anticipated by claim 12 of patent '619, it is not patentably distinct from claim 12 of patent '619.

28. In reference t claim 14 of the current application, the difference between claim 14 of the current application and claim 12 of patent '619 lies in the fact that the patent claim 12 includes many more elements and is thus much more specific. Thus the invention of claim 12 of patent '619 is in effect a "species" of the "generic" invention of claim 14 of the current application. It has been held that the generic invention is "anticipated" by the "speices". ***See In re Goodman,* 29 USPQ2d 2010 (Fed. Cir. 1993).** Since claim 14 of the current application is anticipated by claim 12 of patent '619, it is not patentably distinct from claim 12 of patent '619.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art unit 3772

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7/9/07